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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/537,338 | 11/21/2005 | Yorihiro Yamamoto | ITO-100-PCT | 3453 |
| 28892 7590 05/16/2007 SNIDER & ASSOCIATES P. O. BOX 27613 WASHINGTON, DC 20038-7613 | | | EXAMINER PETERSEN, CLARK D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1657 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,338

Applicant(s)

YAMAMOTO ET AL.

Examiner

Clark D. Petersen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the amendment, filed 9 March 2007, in which claims 1-18 were canceled and new claims 19-22 were presented.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

All objections and rejections not repeated in the instant Action have been withdrawn due to Applicant's response to the previous Action.

Specification

Applicants' amendment to the specification is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This is a new rejection necessitated by Applicants' amendment. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, claim 22 recites that the electrochemical detector is an ultraviolet detector. At page 10 of the specification it is recited that "An analysis system 10 according to the present

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embodiment includes a liquid-sending mechanism 12, a switching mechanism 14, a concentration column 16, a separation column 18, a reduction column 20, an electrochemical detector 22, and an ultraviolet absorption detector 24.” Hence, the electrochemical detector and ultraviolet detector are distinct elements in the system, not the same thing.

Moreover, Mosca et al (Anal Biochem, published online 25 April 2002) state that ubiquinol cannot be detected at 275 nm (see p. 53, col. 1, for example). Because Applicants do not teach a specific wavelength of UV light for measuring ubiquinol, and prior art teaches against the feasibility of measuring ubiquinol using the standard wavelength of 275 nm, the instant specification is not deemed to provide support for the system recited in instant claim 22.

Response to arguments - 35 USC § 112

Applicants traverse the rejection of the phrase “coenzyme Q-10 and a 2-electron reduced form thereof”. Based on Applicants’ arguments, this rejection is withdrawn.

Based on Applicants’ amendment, all other rejections under 35 USC 112, second paragraph, presented in the Office Action dated 13 September 2006 are withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Edlund (J Chromatogr, 1988).

This rejection was previously presented in the Office Action dated 13 September 2006, and is slightly modified as necessitated by Applicants' amendment.

Edlund teaches a method of measuring coenzyme Q₁₀ in human plasma that involves extracting coenzyme Q10 with an organic solvent, namely 1-propanol, from human plasma (see *Preparation of Plasma Samples*, pp. 90-91, for example), which for the purposes of instant claim 19, is deemed to have a polarity comparable to 2-propanol because Edlund teaches that extraction of ubiquinone or ubiquinol requires a water-miscible organic solvent. In one embodiment this method is carried out with 2-propanol (see Table II, p. 92, for example), which he deems not as ideal for extraction as 1-propanol. However he states that it is superior to other polar organic solvents, including ethanol, acetone and acetonitrile. He also states that extraction efficiency is correlated with lipophilicity, a property inversely correlated with polarity (see text, p. 92). Therefore Edlund teaches that 1-propanol has a polarity comparable to 2-propanol, and thus he recites both limitations of claim 19, i.e. that extraction is performed with either 2-propanol or an organic solvent of comparable polarity. In particular he thaws the plasma samples, extracts the coenzyme Q10 and for 45 minutes the samples remain in a liquid form before HPLC injection, meeting the limitation that the extracted samples must be stored at a temperature between their melting point and room temperature (see *Preparation of Plasma Samples*, pp. 90-91, for example). Edlund also teaches a column switching method whereby the sample can be sent through a precolumn which removes polar compounds and strongly retained solutes, removing a fraction of the sample and by definition concentrating the sample, meeting

the limitation of condensing the sample by a column switching mechanism (see p. 90, for example). The detection system employed by Edlund comprises a coulometric system, whereby once the sample has been purified and condensed, it is oxidized, then reduced and then reoxidized, and it is measured at each step, reading on reducing the sample and detecting the reduced form (see p. 90, for example). Therefore the teachings of Edlund are deemed to anticipate instant claims 19-21.

Response to arguments - 35 USC § 102

Applicants traverse the rejection of claims 1-16 in the Office Action dated 13 September 2006 under 35 USC 102(b) as being anticipated by Edlund.

Applicants argue that Edlund does not teach a reducing column. However Edlund teaches that an effluent is passed through housing containing electrochemical detectors that measure the reduced form ubiquinol. A housing through which an effluent is passed defines a column. The effluent is contained within the detector housing, where it is reacted and measured. Therefore Edlund does, in fact, teach a reducing column. Furthermore, as stated by both Edlund and Grossi, et al, measurement of ubiquinol is well known in the art and multiply documented. It is well known in the art to reduce ubiquinone to ubiquinol before measurement, and that this can be achieved with sodium borohydride for example, and it is well known in the art that samples can be exposed to varying conditions within columns; this is, in fact, the purpose of columns, i.e. for separations and for chemical modification of analytes of interest.

Conclusion

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

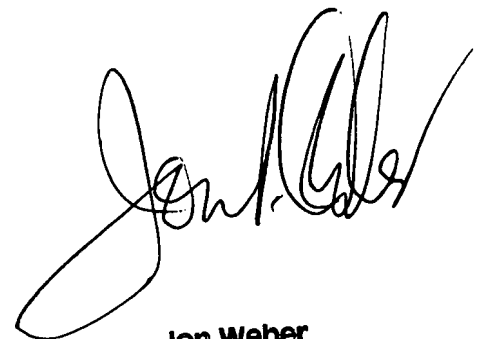
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571)272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDP
5/7/2007

A handwritten signature in black ink, appearing to read 'Jon Weber', is written over a large, faint, circular watermark or stamp.

Jon Weber
Supervisory Patent Examiner